IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACCORD HEALTHCARE INC., et al., Defendants.	C.A. No. 18-1043-LPS REDACTED PUBLIC VERSION FILED ON 2/26/2019

OPENING BRIEF
IN SUPPORT OF NOVARTIS'S MOTION
FOR A PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

The U.S. Patent and Trademark Office has found the patent in this case valid not once, but twice—first when issued, and again after an *inter partes* review. No defendant should be allowed to launch infringing generic drugs in the face of this doubly-confirmed patent.

U.S. Pat No. 9,187,405 claims a method for using 0.5 mg daily of fingolimod to treat relapsing-remitting multiple sclerosis (RRMS). In February 2017, generic drug makers challenged the 405 Patent in an IPR. The Patent Office rejected that challenge after a full trial. The Office found the inventors had discovered that patients needed less than half the fingolimod thought necessary in June 2006. Their discovery earned patent protection.

Novartis now uses that invention in Gilenya®, a top-selling product with about $1.8 billion in annual U.S. revenue alone. Twenty-three generic drug makers have filed ANDAs to sell a generic version. Immediately after the IPR, Novartis sued these companies to protect the exclusivity granted by the 405 Patent. That suit usually would have triggered an automatic 30-month stay of FDA approval, but the Hatch-Waxman stay does not apply here. And while a different patent currently protects Gilenya's exclusivity, that protection will expire in August 2019, seven months before the scheduled March 2020 trial in this case.

The Court thus ordered defendants to say whether they would agree not to launch before final judgment. Most defendants have agreed, but some have not. This motion asks the Court to enjoin those resistant defendants from launching until the case can be fully and finally resolved. The standards for a preliminary injunction are easily met.

First, Novartis is likely to succeed on the merits. Infringement is clear. The 405 Patent covers Gilenya's exact use, which the ANDAs adopt. Validity, too, is assured. The law

presumes patents valid, plus the Patent here has already survived an IPR attack. Defendants' challenges indeed overlap heavily with the references, facts, and theories in the IPR.

For instance, defendants' Invalidity Contentions say Novartis's announcement in April and May 2006 of an upcoming Phase III trial invalidates the Patent. The IPR petitioners had similarly argued the announcement made the Patent obvious. The Office was unpersuaded. The 405 Patent's central claim is that 0.5 mg daily would treat RRMS. The Phase III notices said nothing about whether it would. The 0.5 mg dose had *never* been tested in MS patients before—the prior Phase II trial had tested only higher doses. And as the Patent Office found, pharmacology papers at the time taught away from 0.5 mg. [redacted]

By June 2006, only the inventors had shown the dose could work, through their innovative use of an RRMS animal model. Their research shifted focus to an unexplored mechanism of action to reveal new dosing possibilities others could not see. The Patent summarizes their discovery, which amply enables the claims (and thus disposes of another meritless challenge here). Defendants also question the Patent's written description, arguing the specification lacks support for the claims' exclusion of a loading dose. But the Patent Office expressly found otherwise, and defendants offer no reason to undo that ruling. For these and other reasons below, Novartis is likely to succeed on the merits.

Second, Novartis would suffer irreparable injury without an injunction. Irreversible price erosion, loss of market share, damage to goodwill, and the elimination of critical patient services would follow from a generic launch. For instance, patients must undergo extensive

testing when taking Gilenya for the first time, or when restarting therapy. Novartis provides services to help, but generic entry would make those offerings unsustainable, [redacted] In turn, the fingolimod share of the MS market is likely to shrink, and Novartis's goodwill will suffer. For this and other reasons below, irreparable injury would be inevitable if any generic is allowed to launch-at-risk.

Third, the balance of equities and the public interest weigh in favor of an injunction. On the balance of equities, premature generic entry would cost Novartis billions in unrecoverable losses. In contrast, for the generics, the combination of price declines and dividing up the market would mean the potential revenues foregone by each would be small. On the public interest, the potential injury to patients in losing access to Novartis's critical Gilenya support services decisively weighs in favor of an injunction.

FACTS

The facts here are in expert declarations from MS clinicians and researchers Drs. Lawrence Steinman (Steinman Dec.) and Fred Lublin (Lublin Dec.); pharmacologist Dr. William Jusko (Jusko Dec.); and economist Dr. Chris Vellturo (Vellturo Dec.). Drs. Steinman, Lublin, and Jusko also testified in the IPR. In addition, Novartis submits a declaration from Arvashni Seeripat, Director of MS Marketing (Seeripat Dec.), plus exhibits attached to the declaration of Mr. Robert W. Trenchard (all "Ex." references are exhibits to this declaration). Among these is the IPR final decision (Ex. 73), which also provides important facts here.

The State of the Art in June 2006

RRMS. MS is a terrible disease that mostly strikes women 20 to 40 years old. RRMS is the most common form. The initial cause is a mystery, but once triggered lymphocytes in the bloodstream start to attack and eventually degrade the central nervous system. Symptoms

can "include tremor, paralysis, loss of bladder or bowel control, fatigue, pain, loss of cognitive function, disturbances in vision and speech, emotional changes, and nystagmus." These effects manifest over years with "clearly defined disease relapses with full recovery or with sequelae and residual deficit upon recovery." Patients vary widely in relapse frequency, symptoms, and recovery. (Thomson, Ex. 3 at 158-59; see also Steinman Dec. ¶¶ 24-37; Lublin Dec. ¶¶ 29-35; IPR, Ex. 73 at 5-6.)

Fingolimod. Fingolimod is an immuno-modulator discovered in the early 1990s. By June 2006, Scientists generally thought fingolimod worked by disrupting chemical signals that cause lymphocytes to enter the blood stream from lymphatic tissue. Papers reported that the resulting drop in circulating lymphocytes might protect against organ transplant rejection and autoimmune diseases. (Steinman Dec. ¶¶ 5, 38-45; Jusko Dec. ¶¶ 27-34; IPR, Ex. 73 at 6.)

However, studies showed that only high lymphocyte suppression correlated with therapeutic benefit. Organ transplant studies reported efficacy at only 80% suppression or higher. And in an established RRMS model, a team from pharmaceutical giant Merck had found that "a threshold of about 70% depletion of peripheral lymphocytes was required to see any efficacy[.]" (Webb, Ex. 26 at 118; *see also* Steinman Dec. ¶¶ 6, 78-86; Jusko Dec. ¶¶ 59-71; IPR, Ex. 73 at 29-36.) Other studies in humans—Kahan 2003 (Ex. 14), Park 2003 (Ex. 72), and Park 2005 (Ex. 10)—showed that only doses of 1.0 mg daily or higher suppressed human lymphocytes by 70% or more. Lower doses—including 0.5 mg—fell short of that threshold. In other words, the published data taught away from using 0.5 mg to treat RRMS. (Steinman Dec. ¶¶ 138-146; Jusko Dec. ¶¶ 133-46; Lublin Dec. ¶¶ 47-50; IPR, Ex. 73 at 29-36.)

The Invention and the Patent

Novartis scientists Peter Hiestand and Christian Schnell were able to adapt an RRMS animal model called the "EAE" system to discover that the conventional wisdom was wrong.

Prior EAE Studies. EAE models work by injecting rodents with proteins from other rodents' nervous systems. That triggers the recipient's immune system to attack those proteins, including in its own nervous system. An MS-like condition follows, and drugs can then be tested in the EAE animals. These models thus "simulate the clinical and pathological hallmarks of MS and can provide the necessary predictive index for clinical therapeutic application." (Virley, Ex. 8, at 639; Steinman Dec. ¶¶ 71-75.)

Early fingolimod EAE studies had been published in abstracts or in full scientific papers. Dr. Steinman summarizes eight studies that showed it took daily doses of 0.1 mg/kg or higher to inhibit the disease. No study before June 2006 reported any efficacy at a lower dose. (Steinman Dec. ¶¶ 76-77 (collecting studies).)

The Invention. But the inventors here were able to show EAE efficacy at doses 58% lower. They found that 0.3 mg/kg once-a-week prevented or reduced relapses, which translated into a daily dose of only 0.042 mg/kg (0.3 divided by 7).

To make their discovery, Hiestand and Schell thought differently about fingolimod's mechanism of action. Others had focused on lymphocyte suppression, but the inventors focused on fingolimod's ability to inhibit angiogenesis (new blood vessel growth). Papers posited a link between angiogenesis and MS, though a prior EAE study had seen no evidence. The inventors' innovative combination of a casting technique and the EAE model proved fingolimod inhibited angiogenesis, and thus disease progression at doses far lower than were effective in prior EAE studies. (Ex. 1 at 10:33-11:2; Steinman Dec. ¶¶ 96-110; Jusko Dec. ¶¶

95-101.) Hiestand and Schnell summarized their discovery in an internal Novartis report. (Ex. 56.)

The Patent. Novartis filed for a patent on these discoveries in June 2006, and the Patent Office ultimately awarded claims to a 0.5 mg daily dose. The Patent stated that fingolimod "fully blocks disease-associated angiogenesis [in EAE] and completely inhibits the relapse phases when administered daily at a dose of 0.3 mg/kg [orally, and t]he same effect is obtained when … administered … every 2nd or 3rd day or once a week." (Ex. 1, 10:65-11:2.) The Patent's claims mirror what the data showed—that lower doses reduce relapses, treat

symptoms, and slow progression of the disease. The claimed 0.5 mg daily dose was 60% lower than 1.25 mg, the lowest dose shown to be effective in earlier Phase II RRMS trials. That nearly matched the 58% lower EAE dose the inventors saw in their experiments. (Steinman Dec. ¶¶ 2, 7, 102; Jusko Dec. ¶ 6, 187-88.)

The Fingolimod MS Clinical Trials

While the inventors were making their discovery, Novartis was separately reporting Phase II results and announcing future Phase III clinical trials.

The Phase II study had examined 1.25 and 5.0 mg daily doses for six months in 281 RRMS patients. The doses turned out to show equal promise, each reducing relapse frequency by over 50%. Novartis announced these findings in three documents—Kappos 2005 (Ex. 5), Maunz (Ex. 78), and the Kovarik Abstract (Ex. 77).

[redacted]

Novartis first announced the plan to pursue a two-year Phase III "FREEDOMS" trial in April and May 2006 in the Novartis Press Release (Ex. 69). 6-K (Ex. 79), Chavez (Ex. 34), Goodman (Ex. 85), and Kappos 2006 (Ex. 76). Most of these documents said the Phase III study was simply designed to "confirm" the Phase II results, which had not included a 0.5 mg dose. As another paper observed, a lower 0.5 mg dose would just be "evaluated." In addition, the same two doses were included in two other Phase III studies, "TRANSFORMS" and "FREEDOMS II." (Lublin Dec. ¶¶ 72-75; Steinman Dec. ¶¶ 117-20.)

[redacted]

Much to the investigators' surprise, the 0.5 mg daily dose was fully effective—just as the inventors here had discovered years earlier. The FREEDOMS and TRANSFORMS results were published in the New England Journal of Medicine in 2010, and FREEDOMS II not long after. (Lublin Dec. ¶¶ 3, 85-91; Steinman Dec. ¶¶ 118-20.)

The IPR

Defendant Apotex filed an IPR petition challenging the Patent on February 3, 2017; the Patent Office instituted the petition on July 18, 2017; and three other petitioners

(Teva/Actavis, Sun, and Argentum) later joined the proceeding. After a year-long trial, the Patent Office issued a final written decision on July 11, 2018 upholding all claims.

First, the Patent Office rejected both obviousness grounds, finding that the prior art taught away from the invention. Webb (Ex. 26) said fingolimod had to suppress lymphocytes by at least 70% for "any" efficacy, and Kahan 2003 (Ex. 14), Park 2003 (Ex. 72), and Park 2005 (Ex. 10) showed that 0.5 mg would not suppress lymphocytes sufficiently. As a result, a person of skill in June 2006 would have lacked the motivation to pursue a 0.5 mg daily dose, or a reasonable expectation that the dose would succeed. (IPR, Ex. 73.)

The prior art in the petition was not to the contrary: (i) Kovarik (Ex. 2) was a patent application on a general method for calculating a fingolimod "loading dose" for any transplant or autoimmune use, and shed no light on the right daily dose for RRMS in particular (*see* Ex. 2 at 1); (ii) Thomson (Ex. 3) merely summarized other fingolimod RRMS research, and thus was not independently significant (*see* Ex. 3 at 158); (iii) Budde (Ex. 6) reported on a single-dose Phase I safety study in stable renal transplant patients, and said nothing about fingolimod's effects in the sustained use required in RRMS (*see* Ex. 6 at 17); (iv) Chiba (Ex. 4) patented fingolimod's lymphocyte sequestration mechanism—the same mechanism that pointed away from doses lower than 1.0 mg daily (*see* Ex. 4 at 2:35); and (v) Kappos 2005 (Ex. 5) reported that 1.25 and 5.0 mg daily of fingolimod worked well in the Phase II RRMS trial, but said nothing about whether a lower dose would be effective (*see* Ex. 5 at II/41).

In addition to the instituted references (and many others—the record contained 178 Exhibits), Petitioners argued that announcement in the Novartis Press Release (Ex. 69) and Chavez (Ex. 34) that Novartis would test a 0.5 mg daily dose in Phase III showed the dose was

obvious, if not anticipated. (*See* Ex. 100 at 8.) The Patent Office was unmoved and did not even bother to address the point in the final decision.

Second, petitioners had argued the Patent was not entitled to the June 2006 priority date and was thus anticipated by final Phase III results in 2010. Petitioners said the priority date should be ignored because the Patent's specification did not provide sufficient support for the claims' exclusion of a loading dose under 35 U.S.C. § 112. But based on undisputed testimony by Drs. Steinman and Jusko, the Patent Office disagreed. (Ex. 73 at 44.)

This Case

Immediately after the Patent Office decided the IPR in July 2018, Novartis filed complaints against every generic drug maker that had served a Paragraph IV notice challenging the Patent. To ensure an orderly proceeding, the Court ordered defendants to disclose by January 2, 2019 whether they would agree to stay off market until after the final disposition of the case. (D.I. 216 ¶ 9.) [redacted]

Defendant's Non-Infringement Contentions argue that an invalid patent cannot be infringed and one other theory addressed below. (Exs. 181-89.) Defendants' Invalidity Contentions argue that the Patent was anticipated by Novartis's Phase III clinical trial announcements; is rendered obvious by those announcements and other references; is not enabled or useful for lack of data showing human efficacy; and lacks written description.[2] None of these arguments has any merit.

[1] [redacted]

[2] Defendants served First Supplemental Invalidity Contentions in the afternoon on February 14, 2019, essentially one and a half business days before these papers were due. Novartis

ARGUMENT

35 U.S.C. § 283 gives district courts authority to "grant injunctions in accordance with the principles of equity[,]" including "preliminary injunctions." *High Tech Med. Instrumentation v. New Image Indus.*, 49 F.3d 1551, 1554 (Fed. Cir. 1995). "A decision to grant or deny a preliminary injunction … is within the sound discretion of the district court[.]" *Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368 (Fed. Cir. 2006). "The district court analyzes four factors when considering a preliminary injunction: (1) likelihood of success on the merits, (2) irreparable harm, (3) balance of hardships, and (4) public interest." *Celsis InVitro v. CellzDirect*, 664 F.3d 922, 925-26 (Fed. Cir. 2012). All of these factors weigh in favor of a preliminary injunction here.

I. Novartis Is Likely To Succeed on the Merits

A patentee shows a "likelihood of success" when the patentee is likely to "prove infringement" and "withstand the validity challenges presented by the accused infringer." *Amazon.com v. Barnesandnoble.com*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). So it is here.

A. Defendants' Proposed Generic Gilenya Products Infringe the 405 Patent

Dr. Lublin's declaration shows that the proposed label of every defendant at issue here meets the Patent's claims. (Lublin Dec. ¶¶ 133-149.) Labels that disclose all the claimed elements infringe as a matter of law. *See Orexigen Therapeutics, Inc. v. Actavis Laboratories FL, Inc.*, 282 F. Supp. 3d 793, 816 (D. Del. 2017) (infringement where the "product meets all

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reserves the right to supplement or respond in reply to the new issues therein, including their derivation allegations and contentions based on the 2006 ANN slides.

limitations in the claim and the label instructs on administering the product in the amount and with the frequency recited in the claim.").

Some defendants contend that the labels' silence about a loading dose defeats infringement, because the claims exclude a loading dose. (Ex. 181 at 7; Ex. 183 at 8-10; Ex. 184 at 7; Ex. 185 at 9-10, 12; Ex. 186 at 3; Ex. 188 at 7; Ex. 189 at 3-5.) This theory is specious. Drs. Lublin and Steinman show that a doctor reading these labels would understand not to use a loading dose. (Lublin Dec. ¶¶ 143-145; Steinman Dec. ¶¶ 11, 180-85.) FDA rules require drug labels to describe a dosing regimen in full. Format Labeling, 21 C.F.R. § 201.57(a) (2006) (requiring a "summary of the information . . . including the recommended dosage regimen, starting dose, dose range, . . . and other clinically significant clinical pharmacologic information."). Nothing in the labels says to use a loading dose, and no doctor would. Fingolimod has certain side-effects that could be exacerbated by large up-front doses. (Lublin Dec. ¶¶ 131-132; *see also* Steinman Dec. ¶¶ 184.) A person of skill thus would read the labels to instruct a "daily" dose alone.

Defendants here offer nothing more on infringement, other than to say that an invalid patent cannot be infringed. (Ex. 182 at 4-8.) That theory fails as a matter of law. See *Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920, 1929 (2015) ("invalidity is not a defense to infringement").

B. The 405 Patent Is Presumed and Is In Fact Valid, as the Patent Office Found in the IPR

To assess validity in the preliminary injunction context, the court "must determine whether it is more likely than not that the [patent] challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid." *Titan Tire Corp. v. Case New*

Holland, Inc., 566 F.3d 1372 (Fed. Cir. 2009). The patent thus "enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation[.]" *Id*. at 1377; *see The Research Foundation of State Univ. of New York v. Mylan Pharm. Inc.*, 723 F. Supp. 2d 638, 659 (D. Del. 2010) (applying presumption of validity in preliminary injunction).

Defendants are highly unlikely to overcome that presumption here, especially in view of the IPR decision. "It is well-established that in … a motion for preliminary injunction … the patent holder may use a prior adjudication of patent validity involving a different defendant as evidence supporting … likelihood of success on the merits." *Hybritech Inc. v. Abbot Laboratories*, 849 F.2d 1446, 1452 (Fed. Cir. 1988)[3] For that reason, "the district court … may give considerable weight to a prior adjudication of validity in determining the likelihood of success on the merits on the issue of validity in the preliminary injunction proceeding before it." *Id*.[4] The issues in the second case need not even overlap with the first case completely, as in *Atlas Powder Co. v. Ireco Chemicals*, 773 F.2d 1230, 132 (Fed. Cir. 1985) (even though prior case did not address same issues, "[defendant] has persuaded neither the Kansas district court nor this court that the previous adjudication is insufficient evidence to establish a likelihood of success on the issue of validity").

Here, the overlap with the IPR is substantial. Two thirds of the contention references were in the IPR record. The remainder add nothing materially new. As Drs. Steinman and

[3] *See also Avery Dennison Corp. v. Alien Tech. Corp.*, 626 F.Supp.2d 693, 703 (N.D.Ohio 2009) ("the PTO's action on a request for reexamination is directly relevant" to the likelihood of success on the merits).

[4] *See also Upjohn Co. v. Riahom Corp*, 641 F.Supp. 1209, 1218 (D. Del. 1986) ("A patent holder seeking a preliminary injunction can make a sufficient showing of patent validity [by] . . . a prior adjudication of the validity of the patent.").

Jusko show, the references in defendants' Invalidity Contentions but not in the IPR add nothing material to those that were. (Steinman Dec. ¶¶ 4, 153-76, Jusko Dec. ¶¶ 1-6, 150-73.) Even defendants' 112 written description attack was rejected in the IPR. (Ex. 73 at 40-41.)

While defendants' legal theories and reference combinations sometimes vary from those in the IPR, that does not matter. Those differences merely show that the IPR petitioners did not think those theories worth pursuing. A good example is defendants' argument that Chavez and the other Phase III announcements anticipate the Patent.[5] [redacted] yet chose not to pursue that argument in the IPR in 2017 (Ex. 171).

The one idea in the Invalidity Contentions not already covered to some extent by the IPR is defendants' enablement/utility attack. As shown below (at 21-22), it has no merit. Accordingly, the IPR decision weighs heavily in favor of a preliminary injunction here.

1. The Patent Claims Novel Ideas Not Anticipated in any Prior Art

Defendants' theory that the Phase III trial announcements anticipated the Patent has no merit on its own terms. "[T]he publication will not anticipate the claim if…not enabling" and "[t]o anticipate…, a prior printed publication must contain each and every limitation of the claimed invention[.]" *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.*, 438 F. Supp.

[5] As shown above (at 9), the IPR petitioners argued that Chavez made the Patent obvious. Petitioners also suggested in passing that Chavez anticipated the Patent, though they did not elaborate. (Ex. 100.) The Patent Office had the discretion to take up that theory. *See Genzyme Therapeutic Products Limited Partnership v. Biomarin Pharmaceutical Inc.*, 825 F.3d 1360, 1366 (Fed. Cir. 2016) (PTO may rely on new theory and "as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA."). The Patent Office did not do so.

2d 479, 485-486 (D. Del. 2006). The Phase III trial notices described a plan to test the 0.5 mg dose that had never before been given to RRMS patients. Those notices were neither enabled nor recited all claim elements.

a. The Patent's Claims Require Using 0.5 mg to Treat RRMS

The invention's essential core is the discovery that less fingolimod than previously thought could be used to treat RRMS. Each claim's preamble captures that insight, and describes different aspects of the disease that can be treated. (Jusko Dec. ¶¶106-114.) Claims 1 and 2 are to a method of preventing, reducing, and alleviating relapses; claims 3 and 4 are for generally treating the disease; and claims 5 and 6 are for slowing disease progression. The Patent Office found these preambles to require that 0.5 mg daily of fingolimod be given for the purpose of producing each of the claimed effects. (Ex. 73 at 15; Lublin Dec. ¶¶ 5-7, 94-108; Steinman Dec. ¶¶ 126-134.)

Just as the IPR petitioners had argued, however, defendants contend that the preambles are not limiting. That is wrong, as the Patent Office found and as Novartis will show in claim construction briefing that will occur contemporaneously with this motion. The claims require at least the purpose to treat found by the Patent Office, if not also an actual effect in some patients. Nothing in the Phase III announcements revealed this central part of the invention.

b. The Phase III Announcements Lack Enablement and Thus Cannot Anticipate

The Phase III trial announcements were simply too theoretical to enable the use of 0.5 mg of fingolimod as an RRMS treatment in June 2006. Unlike the 1.25 mg dose in the Phase III trial, the 0.5 mg dose had never been used in an RRMS patient before. Trial designers predicted difficulty in recruiting participants to a trial with an untested dose. The available

science said the dose was unlikely to work, as the Patent Office found. [redacted]

The Phase III trial announcements were thus far more theoretical than the reference found insufficient by this Court in *GSK v. Glenmark.* The "Kelly" reference there described the claimed methods' successful use in Phase II human trials, and a plan for further testing in Phase III. *See GlaxoSmithKline LLC v. Glenmark Pharm. Inc., USA*, 2017 WL 8944995 at *2 (D. Del. May 2, 2017) (describing Kelly as disclosing positive data about the method), *report and recommendation adopted*, 2017 WL 2290141 (D. Del. May 25, 2017); *see also* David T. Kelly, *Carvedilol in Heart Failure*, 82 Suppl. 3 Cardiology, 45–49 (1993). Nonetheless, this Court found Kelly theoretical enough to defeat summary judgment on anticipation, *GlaxoSmithKline LLC v. Glenmark Pharm. Inc., USA*, 2017 WL 2290141 at *3 (D. Del. May 25, 2017); the jury found the reference too theoretical to be enabled, *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582, 585 (D. Del. 2018); and the Court found that verdict amply supported in denying JMOL as to validity. *Id.* at 599.

Here, the Phase III announcements describe a far more uncertain endeavor than what Kelly described in *GSK*—unlike Kelly, the claimed method here had never been tested in humans before, and the available science suggested the dose would be ineffective. To prove the dose effective based on those announcements alone would have required exactly the "undue experimentation" that defeats enablement. *See GlaxoSmithKline*, 2017 WL 8944995, at *18, *report and recommendation adopted*, 2017 WL 2290141 (D. Del. May 25, 2017). These announcements simply cannot be used to invalidate the Patent.

c. The Phase III Announcements Disclose Only Testing and Not Treatment, and Say Nothing About a Loading Dose

The Phase III announcements further omit two claimed elements in the Patent, another fatal blow to defendants' anticipation theory.

First, the single sentence in the Phase III announcements says the future Phase III program will test 0.5 mg, not administer it for treatment. (Lublin Dec. ¶¶ 114-19; Steinman Dec. ¶¶ 8, 111-14; Jusko Dec. 115-18.) Nothing in the announcements says the dose will be effective. Defendants acknowledge that fact in their Invalidity Contentions, and tellingly try to fill that gap by citing the Phase III results described in Kappos 2010. (Ex. 89 at 7, 67, 69-70.) But anticipation requires that all the claimed elements be in the four corners of the allegedly anticipator reference. So defendants' citation to Kappos 2010 does them no good.[6] To the contrary, it merely highlights what is fatally missing from the Phase III trial announcements.

Second, none of the Phase III announcements say anything about excluding a loading dose, let alone an immediately preceding one as the Patent's claims require. Defendants acknowledge this problem in their Invalidity Contentions, and try to fix it by claiming Novartis

[6] Defendants' Invalidity Contentions do not purport to assert an "inherent" anticipation theory. The words "inherent" or "inherency" are nowhere in the Contentions, waiving any inherency argument. (*See* Novartis's Invalidity Contention Responses, Ex. 102 at 8.) Nor would there be any basis for that theory. *In re Montgomery* expressly holds that inherency in the context of a clinical trial announcement cannot be based on the trial's final results. 677 F.3d 1375, 1378 (Fed. Cir. 2012) ("The HOPE study ultimately found that patients receiving ramipril had a statistically significant reduction in the risk of stroke, but these results were not published until after Montgomery's priority date and thus are irrelevant to an anticipation analysis."). Defendants cite nothing other than those results as suggesting the 0.5 mg dose would work. There accordingly is no basis for an inherency theory.

admitted in the IPR that any reference silent about loading doses would be read by a person of skill to preclude such a dose. (Ex. 89 at 9-10.) Novartis said no such thing.

Novartis argued only that a person of skill would read the *Patent specification*'s description of a "daily" dose to support the claims' exclusion of a loading dose. (*See, e.g.*, Ex. (Jusko, Ex. 28 ¶ 175; Steinman, Ex. 27 ¶¶ 10, 183.) That point applies only to the specification, a fulsome description of the discovery and resultant dosing regimen. As Drs. Lublin (Ex. 29 at ¶¶ 12, 120-25) and Jusko (Ex. 28 ¶¶ 119-24) show, no person of skill would read the short statements in the Phase III trial announcements as necessarily precluding a loading dose. Nothing in those announcements purports to be a complete description of the dosing regimen. Fleeting statements like these can leave out vast amounts of detail about the trials, including dosing regimens. Not so in a patent specification, where a person of skill would expect, and the law requires, the complete dosing regimen to be spelled out.

If defendants want to read a missing element into a putative 102 reference, they must show that the element is "necessarily" present—"possibilities" and "probabilities" will not suffice. *SRI International, Inc., v. Cisco Systems, Inc.*, 179 F. Supp. 3d 339, 354, 358 (D. Del. 2016). Defendants do not even attempt to meet this exacting standard in their Invalidity Contentions, nor could they. The one sentence in the Phase III announcements leaves out vast amounts of detail about the dosing protocol and thus cannot necessarily preclude a loading dose regimen. However unlikely a person of skill might have thought a loading dose to be, the possibility could not necessarily be excluded based on the contents of the Phase III announcements.

2. The Patent Claims an Innovative Dosing Method Contrary to Conventional Wisdom in June 2006, and Was Not Obvious

Section 103 obviousness turns on the *Graham* factors: "the scope and content of the prior art"; the "differences between the prior art and the claims at issue"; the "level of ordinary skill in the pertinent art"; and such objective indicia "as commercial success, long felt but unsolved needs, failure of others, etc." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). "An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art … and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *In re Stepan Company*, 868 F.3d 1342, 1345-46 (Fed Cir. 2017) (citation omitted). The Patent Office found the 405 Patent non-obvious in the IPR, and this Court should reach the same conclusion.

a. The Art Taught Away, Experts Were Skeptical, and the Results Were Surprising

To begin with, the Patent Office has already found that the prior art taught away from the invention. (Ex. 89 at 36.) "'A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.'" *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Circ. 1994)).

Webb taught treating RRMS would require 70% or more lymphocyte suppression for "any" efficacy, and Kahan 2003, Park 2003, and Park 2005 taught that 0.5 mg was unlikely to suppress lymphocytes to that extent. (Ex. 89 at 29-36.) Defendants tellingly say nothing about these facts in their Invalidity Contentions, which do not even mention the Patent Office's findings, much less those references. (*See* Ex. 89 *passim*.) By itself, teaching away defeats

obviousness. In addition, experts were openly skeptical about the 0.5 mg dose, and surprised at the results—factors weighing strongly against the 103 attack.[7]

[redacted] When the dose nonetheless showed equal efficacy to the higher 1.25 mg dose in the trial, the result surprised investigators. (Lublin Dec. ¶¶ 58-69, 76-89; Steinman Dec. ¶¶ 8, 117-20, 186.)

Many of these facts were before the Patent Office in the IPR. (*See, e.g.*, Ex. 29 ¶¶ 51-58.) Defendants have had access to that record for months but nonetheless did not address these facts in their Invalidity Contentions, pretending instead that these objective indicia of non-obviousness do not exist. (Ex. 89 at 52-53.) Defendants' inability to articulate a response to these objective indicia is all the Court needs to know to reject their obviousness challenge.

b. No Reference Contains the Claims' Elements, Provides A Motivation to Combine, or an Expectation of Success

Defendants fail to set out any of the three basic requirements for obviousness.

First, courts "consider motivation to combine and reasonable expectation of success only 'if all the elements of an invention are found in a combination of prior art references[.]'"

[7] *See, e.g., Avanir Pharm., Inc. v. Actavis S. Atl. LLC*, 36 F. Supp. 3d 475 (D. Del. 2014), *aff'd sub nom. Avanir Pharm. Inc. v. Par Pharm. Inc.*, 612 F. App'x 613 (Fed. Cir. 2015) (unexpected results support patentability); *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1335 (Fed. Cir. 2016) ("Doubt or disbelief by skilled artisans regarding the likely success of a combination or solution weighs against the notion that one would combine elements in references to achieve the claimed invention.").

PAR Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186, 1194 (Fed. Cir. 2014)(internal quotation omitted). Here, no piece of prior art connects 0.5 mg of fingolimod to actually treating RRMS. At most, the Phase III trial announcements connect that dose to a test, but not a treatment. That alone defeats any obviousness challenge.

Second, a person of skill would have lacked the motivation to use 0.5 mg of fingolimod to treat RRMS, as the Patent Office found. Dr. Steinman shows (Steinman Dec. ¶¶ 41-77, 123) that researchers in June 2006 had no motivation to use a dose lower than 1.25 mg, which had proven effective in the Phase II trials with tolerable side-effects—even before accounting for the research teaching away from 0.5 mg. When that research is considered, a person of skill would have been affirmatively motivated not to use 0.5 mg to treat RRMS (*id.* ¶¶ 78-93,), [redacted] Dr. Steinman shows that none of defendants' references are to the contrary. (Steinman Dec. ¶¶ 135-146.)[8]

Third, a person of skill would have lacked a reasonable expectation of success in June 2006—again, even before considering the art teaching away. Dr. Lublin shows that Phase III trials in neurological conditions like MS failed at higher rates than in other areas. (Lublin Dec. ¶¶ 34-46, 116-17.) A person of skill would have had little expectation of success in using the

[8] Defendants cite a May 2006 slide set presented by Dr. Kappos. Defendants say the document supports motivation to combine and reasonable expectation of success. (Ex. 89 at 11-12 (citing Ex. 93 at 6-10).) But there is no evidence these slides were published, handed out, or otherwise provided to conference participants. The slide set accordingly is not "prior art" under 35 U.S.C. § 102. *See, e.g., In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989) (student thesis neither indexed nor catalogued not accessible to the public and thus not prior art under 35 U.S.C. § 102). In any event, as Drs. Steinman and Jusko show, the document is consistent with and indeed corroborates the art teaching away from the invention. (Steinman Dec. ¶¶ 143-146; Jusko Dec. ¶¶ 139-43.)

0.5 mg daily dose in June 2006 before that trial was complete. And once the art teaching away is considered, then a person of skill would have thought the dose unlikely to work. Dr. Steinman shows that none of defendants' references are to the contrary. (Steinman Dec. ¶¶ 137-52.)

3. The Inventors' EAE Animal Studies Enabled and Showed the Utility of the Claims

Defendants' Invalidity Contentions challenge the Patent for lack of utility or enablement, due to an alleged lack of data. (Ex. 89 at 53-57.) But defendants ignore that the Patent discloses EAE animal testing data. That is more than sufficient.

"[I]f one skilled in the art would accept the animal tests as being reasonably predictive of utility in humans, evidence from those tests should be considered sufficient to support the credibility of the asserted utility." MPEP 2107.03 (citing *In re Hartop*, 311 F.2d 249 (CCPA 1962); *see also Mitsubishi Chemical Corp. v. Barr Laboratories, Inc.*, 435 Fed. Appx. 927 (pharmaceuticals need not be "safe, effective, and reliable for use in humans" to be patentable). "Courts have accepted tests on experimental animals as sufficient to establish utility." *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324–25 (Fed. Cir. 2009). The same is true for enablement. *See Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1310 (Fed. Cir. 2012) (accepting animal study as enabling patent).

Though unclear, defendants' complaint is that the Patent has no human data. While human data may be needed for FDA approval, it is not needed for a patent. *See, e.g., GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, No. CV 11-046-RGA, 2013 WL 4082232, at *19 (D. Del. Aug. 9, 2013), aff'd, 744 F.3d 725 (Fed. Cir. 2014) ("The FDA requires a more

exacting standard for drug approval than the PTO requires for a showing of utility."). All that is needed is animal data that reasonably correlates with the claims.

There is ample such data in the Patent. As Drs. Steinman (¶¶ 9-10, 71-75, 177-79) and Jusko (¶¶ 7, 9, 186-92) show, EAE is a well-established model. Scientists have used the model in thousands of published studies for decades. And here, the inventors used that model to show that doses 58% lower than any before effective in that model could work. The Patent further expressly correlates the EAE results with doses as low as 0.5 in humans, and that dose is in fact 60% lower than the 1.25 mg dose previously shown to be effective in humans. More than enough animal data is disclosed in the Patent to enable the claims.

4. The Specification Supports Excluding Loading Doses

Defendants' Invalidity Contentions repeat the argument from the IPR that the specification does not support the claims' exclusion of a loading dose under 35 U.S.C. § 112. (Ex. 89 at 57-61.) On that basis, defendants also contend, like the IPR petitioners, that the Patent is not entitled to the June 2006 priority date, and thus is anticipated by Kappos 2010. (*Id*. at 40-41.) These arguments fail for the same reasons they did in the IPR.

"Whether a patent claim satisfies the written description requirement … depends on whether the description 'clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1355 (Fed. Cir. 2015) (internal quotation omitted). "[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. … [T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id*. (internal quotation omitted). As *Inphi* made clear, the same standard applies to so-called "negative limitations"

as in the Patent here. *Id*. at 1356; *see also Ex Parte Parks*, 30 U.S.P.Q.2d 1234 (P.T.O. Sept. 2, 1993) (negative limitation supported by specification).

As Drs. Lublin, Jusko, and Steinman testified in the IPR and affirm again here, a skilled person would understand in context that the specification's description of a 0.5 mg "daily" dose supports the claims' exclusion of a loading dose. (Lublin Dec. ¶¶ 13, 126-132; Steinman Dec. ¶¶ 124-125, 180-85; Jusko Dec. ¶¶ 8, 180-85.) Unlike the Phase III trial announcements, the specification purports to provide a full description of a dosing regimen. "Daily" dosing does not require a loading dose, and good reason would exist not to use one. Fingolimod has first-dose side effects that could make a loading dose risky. As the Patent Office found, these facts more than amply support the exclusion of a loading dose in the claims. (Ex. 73 at 44-45.)

In short, none of defendants' invalidity theories is likely to succeed in rebutting the Patent's presumption of validity. Novartis accordingly is likely to succeed on the merits.

II. Novartis Will Suffer Irreparable Injury Without an Injunction

Novartis would be irreparably harmed if defendants launched before trial. "[T]he patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement which may have market effects never fully compensable in money." *The Research Found.*, 723 F. Supp. at 659 (quoting *Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994). Irreparable harm tends to follow from likelihood of success, as price erosion, loss of market share, and loss of reputation and goodwill all threaten harm that cannot be fully addressed by money damages later. *See, e.g., Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (2017) (irreparable harm after a likelihood of success);

Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1361-62 (Fed. Cir. 2008)(same); *Sanofi-Synthelabo*, 470 F.3d at 1381 (same).

This case is far beyond the norm. Gilenya is one of Novartis's top-selling drugs worldwide with about $1.8 billion annual revenue in the United States. Novartis's and defendants' internal business analyses all predict generic launch will rapidly erode prices and Novartis's market share. (Vellturo Dec. ¶¶ 5, 60-106; Seeripat Dec. ¶¶ 7-10 .) Simply calculating retrospective damages would be uncertain due to the MS market's rapidly-evolving competitive landscape, and the central importance of patient support services in that market. (Vellturo Dec. ¶¶ 119-124.) That alone would justify a finding of irreparable harm, even if a permanent injunction were later granted. *See The Research Found.*, 723 F. Supp. 2d at 660 (finding irreparable harm where "Plaintiffs would lose market share. . . . and would also almost certainly experience lost profits and price erosion.").

And here a permanent injunction after trial would never restore the *status quo*—a quintessential instance of irreparable harm. *See Allergan Sales LLC v. Sandoz, Inc.*, 2018 WL 3675235 at *8-9 (D.N.J. 2018) ("Defendants' entry would cause immediate reduction in market share and price erosion that could not be corrected even if Defendants were later forced to withdraw from the market"); *Indivior Inc. v. Dr. Reddy's Labs.*, 2018 WL 3496643 (D.N.J. July 20, 2018) ("Indivior will likely lose market share to DRL's ANDA product once it is launched and will be unlikely to recover that share, even if that product is pulled from the market"). Price erosion, market share loss, and other harms could not be undone by a later injunction removing the generic defendants from the market.

A. Gilenya Will Suffer Irreversible Price Erosion

Irreversible price erosion is a classic form of irreparable harm that can support a preliminary injunction. It exists when third-party payers will resist efforts to raise prices later when generics are barred by a permanent injunction, as in *Sanofi-Synthelabo*, 470 F.3d at 1381*; Allergan Sales LLC*, 2018 WL 3675235 at *8-9; and *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 398 (S.D.N.Y. 2000).

Here, the great majority of Gilenya sales are made [redacted] Novartis's relationships [redacted] with those payors make it unlikely Novartis could ever raise its prices back to original levels. (Vellturo Dec. ¶¶ 45-55, 69-74, 112.) Moreover, Gilenya competes in the solid oral RRMS market with two other drugs (Aubagio® and Tecfidera®), with other potential entrants on the horizon. (Vellturo Dec. ¶¶ 39-41; Seeripat Dec. ¶¶ 28,42,45.) The first generic in the oral market is expected to lower prices across the board, including for Gilenya's competitors; when Novartis prevailed in the IPR last year, press reports said the result would benefit other RRMS drugs (Vellturo Dec. ¶ 71), and analysts came to the same conclusions (Ex. 103 at 1 (noting benefit to Tecfidera and ozanimod); Ex. 104 at 1 (same)). (Vellturo Dec. at ¶¶ 60-75.) If the defendants' ANDA products were later removed from this disrupted market, Novartis would have to compete against Aubagio and Tecfidera a prices lowered due to defendants' infringement. (Vellturo Dec. ¶¶ 71-74.) This manifestly unfair result can be addressed only if prevented in the first place. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996) ("Competitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction… Requiring

purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.").

B. Fingolimod Would Suffer Long Term Loss of Market Share

Novartis would also suffer long-term loss of market share, another classic irreparable harm. Market share losses are exceedingly difficult to redress with a damages award.[9] Gilenya requires extensive patient baseline tests and monitoring upon taking the first dose, or upon restarting after a sufficient break. (Lublin Dec. ¶¶ 14, 92-93; Seeripat Dec. ¶¶ 14-15.) To help ease the process for new patients, Novartis built the Gilenya Go Program, supported by an extensive network of Novartis employees, third-party contractors, and hundreds of physical sites nationwide. (*Id*. ¶¶ 11-21.) Physicians send [redacted] new Gilenya patients through the Go Program each year. (*Id*. ¶¶ 13.) Given Gilenya's initial burdens, physicians would be hesitant to prescribe Gilenya without the services Novartis offers.[10] (*Id*. ¶¶ 27-28.) [redacted]

[9] *See Abbott Labs*, 544 F.3d at 1361-62 (finding that market share and revenue loss caused by entry into the market of an additional generic producer was sufficient to show irreparable harm); *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc.*, 609 F.Supp.2d 786, 811 (S.D. Ind. 2009) ("loss of market share and revenue… will be difficult, if not impossible for Lilly to recover, even if the Court were to later rule in favor of Lilly and Teva's generic raloxifene product was removed entirely from the market").

[10] Ex. 105 at 1 ("the attribute neurologists care most about in a next-gen S1P therapy is the absence of first dose monitoring").

In part for these reasons, generic entry would likely shrink the overall fingolimod market in favor of other drugs without the same burdens. (Vellturo Dec. ¶¶ 92-97; Seeripat Dec. ¶¶ 27-28.) Even after a permanent injunction, Novartis would likely not be able to recapture patients who were prescribed competing drugs, as patients tend to stick with a new medication once started. (Vellturo Dec. ¶¶ 103-04; Seeripat Dec. ¶¶ 41-42; Ex. 103 at 1 ("MS therapies tend to be somewhat sticky – with [patients] switching due to disease activity and tolerability issues but not formulary prioritization").) That result can readily support a finding of irreparable harm. *See TiVo Inc. v. EchoStar Commc'ns Corp.*, 446 F. Supp. 2d 664, 669–70 (E.D. Tex. 2006) (irreparable harm due to long-term loss of market share in part due to "sticky" customer behavior).

Novartis's market share losses likely would also persist because the extensive Gilenya sales and marketing organization would be harmed upon a loss of exclusivity. (Vellturo Dec. ¶¶ 33-34, 98-102; Seeripat Dec. ¶¶ 34-36.) Even if Novartis could instantly re-engage the marketing organization or the Go Program stakeholders at the moment of a permanent injunction, time would be needed to rebuild each. (Vellturo Dec. ¶¶ 105; Seeripat Dec. ¶¶ 43-46.) None of these harms could be remedied after the fact by a damages award or a permanent injunction. (Vellturo Dec. ¶¶ 5, 103-06, 119-24.)

C. Novartis Would Suffer Irreversible Harm in Other MS Products

Novartis will soon launch two new MS drugs, siponimod (Mayzent) and ofatumumab. [redacted] analysts [redacted] predict that a Gilenya launch-at-risk by generics would jeopardize these drugs at a critical early stage, when they are still trying to gain market traction. (Vellturo Dec. ¶¶ 115-18; Seeripat Dec. ¶¶ 29-33; Ex. 106 at 2 (continued exclusivity "could provide Novartis with the opportunity to launch and establish [siponimod] before further price erosion

in the market").) That would impose yet further irreparable harm on Novartis. *See TiVo Inc.*, 446 F. Supp. 2d at 669–70 (irreparable harm because "plaintiff is losing market share at a critical time in the market's development, market share that it will not have the same opportunity to capture once the market matures").

An early flood of infringing generic Gilenya could impair the growth of these new drugs, depress their prices, or both. (Vellturo Dec. ¶¶ 115-18; Seeripat Dec. ¶¶ 29-33.) The significant lost revenue would also impair Novartis's ability to promote these drugs. (Seeripat Dec. ¶¶ 30.) Novartis has already spent [redacted] to expedite siponimod's approval [redacted] (*Id.* ¶ 33.) Nonetheless, defendants' infringement would still harm these new products, and that harm is unlikely to be quantifiable or redressable in a later damages award. (Vellturo Dec. ¶¶ 5, 115-18.)

D. Novartis Would Suffer Harm to Its Goodwill and Relationships

Finally, Novartis would suffer significant injury to its goodwill and relationships from a generic launch, which cannot be readily measured let alone redressed by money damages. *Albany Molecular Research, Inc. v. Dr. Reddy's Labs.*, Ltd., 2010 WL 2516465, at *11 (D.N.J. June 14, 2010) (weighing such harms in granting a preliminary injunction).

Gilenya is a revolutionary drug that has vastly improved the lives of RRMS patients. It has had a profound positive impact on the perception of Novartis. (Vellturo Dec. ¶¶ 108; Seeripat Dec. ¶¶ 37.) Gilenya has thus been a core part of Novartis's neuroscience branding and marketing, far exceeding mere sales with benefits critical for future drug development. (Vellturo Dec. ¶¶ 108-14; Seeripat Dec. ¶¶ 37.) Commoditizing a drug tends to diminish the perceived connection between the innovator and the drug's benefits. (Vellturo Dec. ¶¶ 109.)

[redacted]

[redacted] (Seeripat Dec. ¶¶ 37-40, 47.) Quantifying these significant and lasting losses would be virtually impossible as part of a patent damages theory. (Vellturo Dec. ¶¶ 5, 107-14.)

III. The Balance of Equities and the Public Interest Favor a Preliminary Injunction

Novartis will suffer a profound and irreversible disruption to a $1.8 billion a year business without a preliminary injunction (not counting Novartis's unquantifiable harms). In contrast, defendants' rosiest projections suggest about [redacted] in collective profit over the same period. (Vellturo Dec. ¶¶ 125-30.) The balance of harms goes only one direction.

So, too, does the public interest. In the typical generic drug patent case, the public interest in lower drug prices balances equally against the interest in innovation. *Research Found. of State Univ. of New York v. Mylan Pharm. Inc.*, 2010 WL 11475865, at *17 (D. Del. July 6, 2010) (J. Stark) ("[T]he public interest in lower-priced drugs is balanced by a significant public interest in encouraging the massive investment in research and development that is required before a new drug can be developed and brought to market."). [redacted]

CONCLUSION

For the foregoing reasons, the Court should preliminarily enjoin defendants Accord, Alkem, Aurobindo, Dr. Reddy's, HEC, Hetero, Mylan, Torrent, and Zydus/Cadila from launching their ANDA products at risk, as reflected in the accompanying proposed order.

Dated: February 19, 2019

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